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10/015,390	12/12/2001	David Botstein	39780-2830.053 US	9959
35489	7590	10/27/2006		
HELLER EHRMAN LLP 275 MIDDLEFIELD ROAD MENLO PARK, CA 94025-3506			EXAMINER FREDMAN, JEFFREY NORMAN	
			ART UNIT	PAPER NUMBER

1637

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/015,390  
Filing Date: December 12, 2001  
Appellant(s): BOTSTEIN ET AL.

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Barrie D. Greene  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed August 15, 2005 appealing from the Office action mailed November 8, 2004.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

6,444,790

YOUNG et al

9-2002

Meric et al. "Translation initiation in cancer: A novel target for therapy" Molecular Cancer Therapeutics, Vol. 1 (Sep 2002), pp. 971-979.

Konopka et al. "Variable expression of the translated c-abl oncogene in Philadelphia chromosome positive B-lymphoid cell lines from chronic myelogenous leukemia patients" Proc. Natl. Acad. Sci. USA, Vol. 83 (June 1986), pp. 4049-4052.

Gokman-Polar et al. "Elevated protein kinase C BII is an early promotive event in colon carcinogenesis" Cancer Research, Vol 61 (15 February 2001), pp. 1375-1381.

Pennica et al "WISP genes are members of the connective tissue growth factor family that are up-regulated in Wnt-1 transformed cells and aberrantly expressed in human colon tumors" Proc. Natl. Acad. Sci. USA, Vol. 95 (December 1998), pp. 14717-14722.

Rost, B. "Enzyme function less conserved than anticipated" J. Molecular Biology, Vol. 318 (2002), pp. 595-608.

Sawiris et al. "Development of a highly specialized cDNA array for the study and diagnosis of epithelial ovarian cancer" Cancer Research, Vol. 62 (15 May 2002), pp. 2923-2928.

Ding, C. "Unsupervised feature selection via two-way ordering in gene expression analysis", Bioinformatics, Vol. 19, No. 10 (2003), pp. 1259-1266.

Li et al. "Zipf's law in importance of genes for cancer classification using microarray data" J. Theoretical Biology, Vol. 219 (2002), pp. 539-551.

#### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33, 38-40 and 44-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Young et al (U.S. 6,444,790).

Young teaches a nucleic acid with 100% nucleic acid sequence identity to SEQ ID NO: 215 as shown in the attached alignment.

This meets the claim limitations of claims 33-34, 38-40 and 48-54.

With regard to claims 44-47, Young expressly teaches expression of the sequence in vectors and host cells including yeast and E. coli (see column 16, line 55 to column 17, line 67).

Claims 33 and 48-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Kang et al (Proc. Natl. Acad. Sci. (August 1998) 92:10078-10082) as evidenced by Genbank Accession No. AF076483 (August 15, 1998).

Kang teaches a nucleic acid which will hybridize to SEQ ID NO: 215 and which is at least 100 nucleotides (see page 10078, bottom right data deposition, where AF076483 is indicated as deposited). Further, Kang's sequence comprises the full length coding sequence "from within" SEQ ID NO: 215. Kang's sequence alignment with SEQ ID NO: 215 is shown below. So while Kang's sequence is not identical to that

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of SEQ ID NO: 215, it will hybridize under any stringency conditions whatsoever and is certainly more than 100 nucleotides in length.

Score = 1298 bits (655), Expect = 0.0  
Identities = 668/671 (99%), Gaps = 1/671 (0%)  
Strand = Plus / Plus

```
Query: 1   tcccggaccctgccgccctgccactatgtcccgccgctctatgctgcttgctgggctct 60
          |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||
Sbjct: 20  tcccggcccctgccgccctgccactatgtcccgccgctctatgctgcttgctgggctct 79

Query: 61  ccccagcctccttcgactcggagcggctcaggagacagaagacccggcctgctgcagccc 120
          |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||
Sbjct: 80  tcccagcctccttcgactcggagcggctcaggagacagaagacccggcctgctgcagccc 139

Query: 121 catagtgtcccggaacgagtggaaggccctggcatcagagtgcgccagcacctgagcct 180
          |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||
Sbjct: 140 catagtgtcccggaacgagtggaaggccctggcatcagagtgcgccagcacctgagcct 199

Query: 181 gcccttacgctatgtggtggtatcgcacacggcgggcagcagctgcaacacccccgcctc 240
          |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||
Sbjct: 200 gcccttacgctatgtggtggtatcgcacacggcgggcagcagctgcaacacccccgcctc 259

Query: 241 gtgccagcagcaggcccgaatgtgcagcactaccacatgaagaca-tgggctggtgcga 299
          |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||
Sbjct: 260 gtgccagcagcaggcccgaatgtgcagcactaccacatgaagacactgggctggtgcga 319

Query: 300 cgtgggctacaacttcctgattggagaagacgggctcgtatacaggggccgtggctggaa 359
          |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||
Sbjct: 320 cgtgggctacaacttcctgattggagaagacgggctcgtatacaggggccgtggctggaa 379

Query: 360 cttcacgggtgccactcaggtcacttatggaaccccatgtccattggcatcagcttcat 419
          |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||
Sbjct: 380 cttcacgggtgccactcaggtcacttatggaaccccatgtccattggcatcagcttcat 439

Query: 420 gggcaactacatggatcgggtgccacaccccaggccatccgggcagcccagggtctact 479
          |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||
Sbjct: 440 gggcaactacatggatcgggtgccacaccccaggccatccgggcagcccagggtctact 499

Query: 480 ggcctgcggtgtggctcagggagccctgaggtccaactatgtgctcaaaggacaccggga 539
          |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||  |||||
Sbjct: 500 ggcctgcggtgtggctcagggagccctgaggtccaactatgtgctcaaaggacaccggga 559
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Query: 540 tgtgcagcgtacactctctccaggcaaccagctctaccacctcatccagaattggccaca 599  
|||||

Sbjct: 560 tgtgcagcgtacactctctccaggcaaccagctctaccacctcatccagaattggccaca 619

Query: 600 ctaccgctccccctgaggccctgctgatccgcacccattcctcccctcccatggccaaa 659  
|||||

Sbjct: 620 ctaccgctccccctgaggccctgctgatccgcacccattcctcccctcccatggccaaa 679

Query: 660 aacccactgt 670

|||||

Sbjct: 680 aacccactgt 690

### **(10) Response to Argument**

#### **Issue 1 - Anticipation under 102(e) of the claims by Young et al, U.S.**

#### **Patent 6,444,790**

There is no dispute that Young teaches a protein which is identical to the protein claimed. The dispute is whether Appellant receives benefit of priority to provisional 60/100,661 and whether the Young et al disclosure itself has utility.

#### **Stempel doctrine**

Appellant cites the Stempel doctrine to overcome the Young rejection. However, the Stempel doctrine does not support Appellant's position because in Stempel, the situation involved a prior art reference which lacked specific utility. That is not the current case, where Young has a specific utility for the molecule at issue. This logic is supported by Stempel, which states in relevant part "unless the reference also teaches how to use the compound it describes (see page 20 of response)." This is precisely that situation. The provisional application 60/100,661 lacks a substantial and specific utility for SEQ ID NO: 216 while the Young patent has a specific and substantial utility

that was unappreciated by Appellant and unknown to Appellant in any of their applications.

Utility due to Granulocyte Peptide A association

Appellant argues that the disclosure of 60/100,661 provides utility by arguing that the provisional identifies the sequence as having homology to granulocyte peptide A, and that this homology provides utility for the sequence. Applicant refers to page 13 of 60/100,661, where lines 15-16 disclose that the protein has 70% identity to granulocyte peptide A. This homology is insufficient to provide utility since, as is noted in the enablement rejection, even very similar proteins, as shown by homology, may have very different functions (see Rost et al (J. Mol. Biol. (2002) 318(2):595-608). There is no showing in the provisional that pro1269 has “microbial activity” and the homology is insufficient to support this as a utility for Pro1269. In fact, the actual utility argued for Pro1269 by Appellant has nothing to do with “microbial activity” and relates to the overexpression of the nucleic acid in cancer cells. So Appellant does not even rely upon the argued “microbial activity” utility in 60/100,661 for utility of this protein in the current application and does not and has not argued this utility for the protein (at least not previously in this application’s prosecution history).

Based upon Example 10 of the utility guidelines, it is clear that where the homology is insufficient to demonstrate that the protein shares the utility of the asserted “homologous partner”, utility will be lacking. Here, where the protein not only has 70% identity with Granulocyte Peptide A, but also has 82% identity with the Bos taurus



oligosaccharide binding protein and 99% identity with the human peptidoglycan recognition protein 1. The association referred to by Applicant with BGP-A is with a protein that in the Selsted patent has 13 amino acids. There is no evidence that the full length protein of Pro1269, which according to Applicant has 70% identity with BGP-A shares the same utility. Since the change of a single amino acid can change the function of a protein, changing a DNA polymerase to an RNA polymerase, or a single amino acid can change a molecular motor protein like Ncd from moving like kinesin to the plus end of the microtubule or moving in the opposite direction to the minus end of the microtubule. These changes significantly effect the utility of the protein and these are single amino acid changes. Applicant is attempting to rely on a short region of homology with 30% different sequence. There is no expectation that the utility will be the same (as per the cited Rost reference).

#### Utility of Young patent

Young is a reference that teaches how to use the compound it describes. However, Appellant argues that Young does not provide utility. This is easily rebutted in two ways. First, the Young patent is literally identical to the provisional from which it depends (60/113,809). The Young patent provides identical utilities for the claimed SEQ ID NO: 4 and for the sequence at issue, SEQ ID NO: 6. Since issued patents are PRESUMED useful and enabled, and no evidence overcoming that presumption has been presented, Young is presumptively enabled for SEQ ID NO: 6 simply based on the fact that the patent issued.

However, the case for utility for SEQ ID NO: 6 is much better than that. Second, the Young patent expressly notes, "The present inventors have discovered that PGRP-K, PGRP-W, and PGRP-C is expressed in keratinocytes, wound healing tissues, and chondrosarcomas, respectively. For a number of disorders of these tissues and cells, such as tumor and tumor metastasis, infection of bacteria, viruses and other parasites, immunodeficiencies, septic shock, apoptosis or proliferation of these tissues, and proper antigen processing and presentation, it is believed that significantly higher or lower levels of the PGRP-K, PGRP-W, or PGRP-C gene expression can be detected in certain tissues (see column 6, lines 48-57)." This is not a hypothetical use but is grounded in the factual expression data determined by Young. Young teaches specific diagnosis of specific disorders including wound healing at column 6, lines 48-67. This is a specific and substantial utility, unlike those presented in the current application. Appellant therefore is incorrect in stating that the specification is devoid of experimental evidence supporting utility. The specification expressly states this diagnostic ability and the differential expression of the protein during wound healing. Diagnosing problems in wound healing is clearly a credible, specific and substantial utility.

The assertion by Appellant that the 60/100,661 specification has identical data to that of Young is therefore not correct. While Young provides specific data on the expression of SEQ ID NO: 6 in tissues involved in wound healing, stating that the present inventors "have discovered" (using the past tense) this association, the specification of 60/100,661 has no such corresponding data.


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**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



JEFFREY FREDMAN  
PRIMARY EXAMINER

10/26/06


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